

REMARKS

Claims 1, 2, 4-6, 8-19, 21-23, 25-43, 57 and 58 are pending in the application with entry of this amendment. Claims 3, 20 and 51-56 are currently canceled. Claims 7, 24, 44-50 were previously canceled without prejudice. Claims 1, 2, 8, 14, 15, 17-19, 25, 29, 33, 34 and 43 are currently amended. The amendments do not present new matter. *See, e.g.*, Figs. 1A-2B; original claims 3 and 20; and various sections of the specification describing use of a filter for collecting and processing a biological specimen to be examined. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicant kindly acknowledges that the rejection of claims 39-42 and 52-55 under 35 U.S.C. §112 has been withdrawn.

Applicant also kindly acknowledges that the rejection of dependent claims 39-42 as allegedly being anticipated by U.S. Patent Application Publication No. 2002/0045272 A1 to McDevitt et al. (“McDevitt”) has been withdrawn.

Further, Applicant acknowledges that the line of argument presented in earlier Office Actions is no longer relied upon for the new grounds of rejection. Thus, it is Applicant’s understanding that it is implicitly conceded that the prior Office Action allegations fail to support the prior rejections. For example, pages 3-4 of the August 21, 2007 Office Action referred to paras. 438, 464, 573 and 574 to allege that claims 1-6, 11, 12, 14, 15, 18-23, 29-31, 33, 34 and 36-38 were anticipated by McDevitt, but following Applicant’s Amendment of November 19, 2007, the current Office Action now relies on other sections of McDevitt, *i.e.*, paras. 552, 558, 569 and 572, in connection with new grounds of rejection of the same and other claims.

II. The Office Action Does Not Specify the Basis of Rejection of Each Claim

Initially, Applicant notes that the Office Action does not explain how various references disclose certain claim limitations. The single paragraph on pages 2-3 of the Office Action that rejects more than 20 claims does not actually specify which component or components of McDevitt allegedly corresponds to each element of each of these claims.

For example, while the Office Action appears to allege that the filter 1040 of McDevitt is a “filter” as recited in claims 1 and 18, these claims (prior to the current amendment) referred to a container for holding a filter, but no section of the Office Action actually specifies which component or components of the system described by McDevitt is allegedly a “container”

(noting that claims 1 and 18 are currently amended to refer to a tray). Further, it appears that it is alleged that a floppy disk drive is a “storage device” as recited in claims 1 and 18, but the Office Action has not explained how a floppy disk drive, which is apparently used with a floppy disk, is a data storage device associated with a container, which has not been specifically identified, and that stores data related to the filter. As another example, claim 29 recites *inter alia* “the processor having a housing, wherein the tray [which defines an aperture for holding a filter] is positionable inside of the processor housing.” However, the Office Action does not state which part of the system described McDevitt corresponds to a “processor housing.” Other examples of general allegations that do not specifically identify components in McDevitt that correspond to specific claim elements are discussed in this Amendment.

If the rejection stands following this Amendment, Applicant respectfully requests the Examiner to set forth with specificity which components of each cited reference (identified by paragraph and line number, and component number) allegedly correspond to each element of each claim such that Applicant may better understand the basis of the rejections. 35 U.S.C. §132 (“Whenever on examination, any claim of a patent is rejected, . . . the Director shall notify the application thereof, stating the reasons for such rejection, . . . together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application . . .”); 37 C.F.R. § 1.194(c)(2) (“In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. . . The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.”).

III. Rejection Based on Ostrup is Moot

Claims 51-56 are canceled without prejudice. Therefore, the rejection based on Ostrup moot. Applicant reserves the right to file a divisional or continuation application with canceled claims.

IV. Claims 1, 2, 4-6, 11, 12, 14, 15, 18, 19, 21-23, 29-31, 33, 34 and 36-38 Are Novel Over McDevitt

Independent claims 1 and 18 and respective dependent claims 2, 4-6, 11, 12, 14, 15, 19, 21-23, 29-31, 33, 34 and 36-38 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by McDevitt. Applicant respectfully traverses the new grounds of rejection and respectfully submits that the rejection is moot in view of claims 1 and 18 as amended.

McDevitt fails to disclose, teach or suggest “a tray defining an aperture for holding the filter within the tray” as recited in claims 1 and 18. As discussed above, the Office Action does

not identify a specific component of the portable sensor array system described by McDevitt that is allegedly a “container” as recited in claims 1 and 18 prior to the current amendment. Nevertheless, McDevitt fails to disclose teach or suggest a tray that defines an aperture for holding a filter.

In contrast, as shown in Fig. 78 of McDevitt reproduced below, the cited reference describes a portable sensor array system having fluid entry ports 1020, 1022, a syringe 1030, nucleopore filters 1040 anchored at a top of the unit, an input device 1012 and a display screen 1014. A sensor array cartridge 1010 is inserted into the array system prior to testing and includes a sensor array having chemically sensitive particles.

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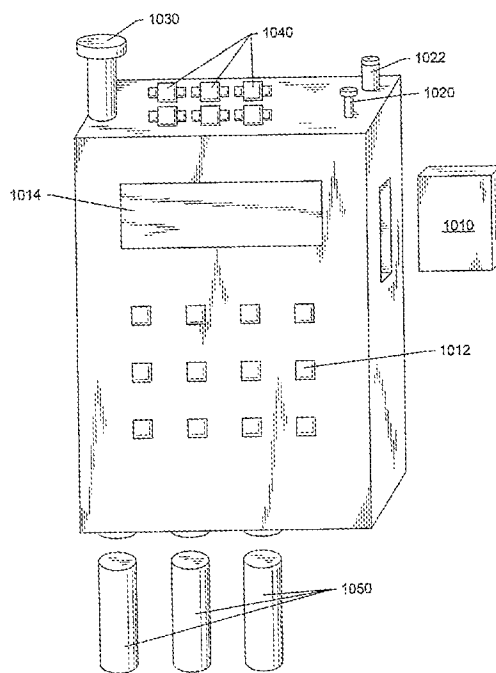


FIG. 78

The sensor array system described by McDevitt, however, is not a tray as this term is generally understood in view of the specification and by persons of ordinary skill in the art. Further, the sensor array system is not a tray that defines an aperture for holding a filter. Instead, the filter 1040 described by McDevitt is “anchored at the top of the unit” and is not positioned within an aperture defined by a tray. McDevitt (para. 555). In fact, McDevitt does not even refer to a “tray” or an aperture defined by a tray. Understandably, the Office Action is also silent in this regard given these deficiencies of McDevitt.

McDevitt also fails to disclose, teach or suggest a tray defining an aperture for holding a “biological specimen filter for collecting a portion of the biological specimen sample to be examined” as recited in claims 1 and 18. It is alleged that the nucleopore filter 1040 described by McDevitt is a “biological specimen filter” as recited in Applicant’s claims. However, as explained by McDevitt, the filter 1040 is used for filtering a sample prior to its introduction into the portable array system, and it is the fluid samples, not what is collected by the filter 1040, which are analyzed using the sensor array system. McDevitt (para. 555) (“samples may be filtered to remove solid particles prior to their introduction into the portable sensor array system.”). In this regard, McDevitt describes a configuration that is the opposite of that recited in claims 1 and 18.

Additionally, McDevitt fails to disclose, teach or suggest “a data storage device attached to or positioned within the tray” and “wherein data related to the filter is stored in the data storage device” as recited in claims 1 and 18. It is alleged that paras. 558 and 569 of McDevitt disclose a “data storage device attached to or positioned within the tray” as recited in Applicant’s claims, and apparently alleged that paras. 574 and 572 disclose such a data storage device, “wherein data related to the filter is stored in the data storage device.” Para. 558, however, appears to describe a display screen 1014 and a data communication system, which may include “a floppy disk drive.” A floppy disk drive, however, is not a data storage device that is attached to or positioned within a tray that defines an aperture for holding a filter. Further, it is well understood, that a “tray” as recited in Applicant’s claims would not have a floppy disk drive. Para. 569 describes a controller and different operations performed by the controller, but does not otherwise refer to a data storage device that stores data related to a filter that is held within an aperture defined by a tray. Instead, the controller operations described in para. 569 relate to determining the type of sensor array in the system, the type of light required and the type of fluids required, collecting data produced during analysis “of the fluid sample,” analyzing the data produced during “analysis of the fluid sample,” producing a list of components present in the “fluid sample” and monitoring sampling conditions.

It is further apparently alleged that paras. 574 and 572 disclose “data related to the filter” that is stored in the data storage device, which is attached to or positioned with in a tray. However, para. 574 explains that the controller can accept information from the user regarding the type of test being performed, and para. 572 explains that the controller can prepare instructions based on the type of analysis to be performed. Again, McDevitt does not disclose,

teach or suggest the combination of “a data storage device attached to or positioned within the tray,” the “tray defining an aperture for holding the filter” and “wherein data related to the filter is stored in the data storage device.” In fact, the section (paras. 545-575) describing a sensor array system with reference to Fig. 78 refers to a “filter 1040” only twice, both times in para. 555.

Consistent with what is actually described by McDevitt, and as would be naturally expected and understood by a person of ordinary skill in the art reading the cited sections of McDevitt, the cited reference describes a filter and a sensor array as different components, in different contexts, and for performing different functions in different sections of the cited reference. Simply because McDevitt describes a data communication system and a controller does not disclose, teach or suggest the combination of “a data storage device attached to or positioned within the tray,” the “tray defining an aperture for holding the filter” and “wherein data related to the filter is stored in the data storage device” as recited in claims 1 and 18.

If the rejection stands following this Amendment, Applicant respectfully requests the Examiner to specify, by paragraph and line number (and words and specific components thereof), where McDevitt actually describes what is alleged since Applicant is not able to identify such a description in the cited paragraphs. Moreover, to the extent that the Office Action alleges that information involving a sensor array is related to a filter located within an aperture of a tray, Applicant again notes that the sensor array unit is not a tray, McDevitt explains that these components are different components used for different purposes, and McDevitt describes these components in different sections of the reference. Applicant further notes the inherency requirements set forth in MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

In view of these deficiencies, Applicant respectfully submits that independent claims 1 and 18 are novel over McDevitt. Dependent claims 2, 4-6, 11, 12, 14, 15, 19, 21-23, 29-31, 33, 34 and 36-38 incorporate the elements and limitations of respective independent claims 1 and 18 and, therefore, are also allowable. MPEP §2143.03. McDevitt is also deficient relative to various dependent claims.

The deficiencies of McDevitt relative to dependent claims 2 and 19 are discussed above. McDevitt fails to disclose, teach or suggest a plurality of biological specimen filters for collecting portions of respective biological specimen samples to be examined, the tray defining a plurality of apertures for holding respective filters, and the data storage device storing data related to the plurality of filters.

With regard to claims 5, 6, 22 and 23, the Office Action appears to refer to a floppy disk drive, but has not explained how a floppy disk drive is a “read only memory” or a “read/write memory” data storage device that is attached to or positioned within a tray that defines an aperture for holding a filter. As explained above, it is well understood, that a “tray” for a biological specimen filter as recited in Applicant’s claims would not have a floppy disk drive as described by McDevitt. If the rejection stands, Applicant respectfully requests clarification of the rejection.

Moreover, McDevitt fails to disclose, teach or suggest “the stored data indicating a specimen that is compatible with the filter” as recited in claims 12 and 31. The Office Action has not identified any section of McDevitt that specifically discloses these claim elements.

McDevitt also fails to disclose, teach or suggest “the stored data indicating a test or a combination of tests that is compatible with the filter” as recited in claims 11 and 30, “the stored data indicating a number of processing steps involving the filter” as recited in claims 14 and 33, and “the stored data indicating one or more parameters of processing steps involving the filter” as recited in claims 15 and 34. Instead, McDevitt explains that a commercially available filter 1040 may be used to remove solid parties from the sample prior to its introduction into the sensor array system. McDevitt (para. 555). McDevitt does not describe stored data as recited in these claims, and the Examiner has provided no explanation that the subject matter of these claims are necessarily or inherently present in McDevitt.

Further, McDevitt fails to disclose, teach or suggest “the processor having a housing, wherein the tray [which defines an aperture for holding a filter] is positionable inside of the processor housing” as recited in claim 29. The deficiencies of the cited reference with regard to

the “tray” and “aperture” elements of independent claim 18 are discussed above. The Office Action does not state which part of the system described McDevitt corresponds to a “processor housing.” Thus, Applicant cannot accurately assess the basis of the rejection. Nevertheless, McDevitt cannot support the rejection since the cited sections are directed to a portable sensor array system for conducting analysis of fluid samples at a testing location. The sensor array system is not a tray and is not positionable inside of a processor housing. If the rejection stands, Applicant respectfully requests the Examiner to specifically identify, by paragraph and line number, and component number, which components are alleged to be a “processor,” a “housing” and a “tray” as recited in claim 29.

With regard to claim 37, para. 558 of McDevitt, the Office Action has not identified a specific component that allegedly corresponds to a mechanical interface as recited in claim 38. If the rejection stands, Applicant respectfully requests the Examiner to specifically identify, by paragraph and line number, and component number, what is alleged to be a “mechanical interface” as recited in claim 37.

Accordingly, Applicant respectfully requests that the rejection of claims 1, 2, 4-6, 11, 12, 14, 15, 18, 19, 21-23, 29-31, 33, 34 and 36-38 under 35 U.S.C. §102(b) based on McDevitt be withdrawn.

V. Claims 16, 17, 35, 39-43, 57 and 58 Are Patentable Over McDevitt

Dependent claims 16, 17, 35, 39-43, 57 and 58 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt. These dependent claims incorporate the elements and limitations of respective independent claims 1 and 18 and, therefore, are also believed allowable. MPEP §2143.03. McDevitt is also deficient relative to various dependent claims.

With regard to claims 16 and 35, it is generally alleged that it would have been obvious to assign a unique registration number to a data storage means of the sensor array described by McDevitt so that it can be identified in case it is replaced. The deficiencies of the “data storage means” and “sensor array” are discussed above. McDevitt does not disclose, teach or suggest, and is not related to, a tray that defines an aperture for holding a filter for collecting a portion of a biological sample to be examined and a data storage device attached to or positioned within the tray and that stores data comprising a unique registration number of the data storage device. Applicant respectfully submits that the allegations on page 5 of the Office Action are moot in view of claims 1 and 18 as amended.

Further, McDevitt teaches away from these dependent claims, which incorporate the

elements of claims 1 and 18, each of which recites *inter alia* “a biological specimen filter for collecting a portion of the biological specimen sample to be examined,” and claims 17 and 43, which recite *inter alia* “the filter comprising a cytological filter for collecting and “examining collected cells” of the biological specimen sample. In contrast, as discussed above, McDevitt explains that the filter 1040 is used for the purpose of filtering a sample prior to its introduction into the portable array system, and the fluid samples, not cells collected by the filter, are then analyzed. McDevitt (para. 555). McDevitt, therefore, describes a configuration that is the opposite of what is recited in Applicant’s claims.

With regard to claims 39-42, it is conceded that McDevitt does not disclose vials for collecting the sample. Office Action (p. 6). Applicant respectfully submits that the coordination between a filter and a vial is not disclosed by McDevitt, particularly considering that McDevitt explains that a commercially available filter 1040 is used. McDevitt (para. 555). Thus, McDevitt does not disclose, teach or suggest, and is not related to, use of codes on a vial and a filter and associated interfaces as recited in claims 39-42.

McDevitt also fails to disclose, teach or suggest “the filter having a cylindrical shape” as recited in claims 57 and 58. Rather, McDevitt explains that commercially available filters 1040 are utilized, and as shown in Fig. 78, they do not have cylindrical shapes. Given this deficiency, it is then generally alleged that it would be obvious to use a filter having a cylindrical shape with reference to para. 121. Para. 121, however, describes a supporting member that is formed using a silicon wafer and cavities 230 that are formed by an anisotropic etching of the silicon wafer. The cavities 230 may be formed such that the sidewalls of the cavities are substantially tapered at an angle of between about 50 to 60 degrees. While depicted as pyramidal, the cavities 230 may be formed in a number of shapes including but not limited to, spherical, oval, cubic, or rectangular. Applicant notes that the dimensions of the cavities that are described are, e.g., on the order of microns. The commercially filter 1040 that is anchored on a top surface of the system as shown in Fig. 78 of McDevitt clearly is not on the order of microns (and is many times larger). Thus, the Office Action allegations are misplaced and not relevant to Applicant’s claims or the filter 1040 in Fig. 78.

Accordingly, Applicant respectfully requests that the rejection of claims 16, 17, 35, 39-43, 57 and 58 under 35 U.S.C. §103(a) be withdrawn.

VI. Claims 8-10 and 25-28 Are Patentable Over McDevitt and Marsh

Dependent claims 8-10 and 25-28 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt in view of U.S. Patent No. 5,219,294 to Marsh *et al.* (“Marsh”). These dependent claims incorporate the elements and limitations of respective independent claims 1 and 18 and, therefore, are also believed allowable. MPEP §2143.03. Marsh is cited for the limited purpose of allegedly disclosing certain connectors and connector configurations and does not cure the deficiencies of McDevitt. Accordingly, the cited references, individually and in combination, cannot support the rejection even if somehow properly combined.

The Office Action has not identified a data storage device (as recited in claims 1 and 18) that is positioned within a recess of a tray as recited in claims 8 and 25. Applicant notes that claims 8 and 25 recite: 1. a tray defining a recess; 2. a data storage device (that stores data related to a filter), and 3. that the data storage device is positioned in the recess. In other words, claims 8 and 25 do not merely recite a connector. Rather, claims 8 and 25 recite that the data storage device is positioned in a recess of a tray, e.g., as shown in Fig. 2B of the subject application.

In view of these claim elements, the basis of the rejection involving a connector for lap top and desk top computers is not clear, and such a connector is not relevant. In this regard, Marsh is not analogous art. More specifically, to rely on a reference under 35 U.S.C. §103(a), Marsh must either 1. be in the field of Applicant’s endeavor, or 2. be reasonably pertinent to the particular problem with which the inventor is concerned. MPEP §2141.01(a). A connector for interconnecting a lap top computer and a desk top computer is not in the field of endeavor of preparing biological specimens. Accordingly, Marsh must be reasonably pertinent to the particular problem with which the inventor is concerned, which it is not.

As discussed in the “Description of Related Art,” Applicant describes, *e.g.*, improving systems that utilize cytological filters by verifying filter expiration, compatibility with specimens and availability of processing information and operating parameters utilizing a container defining a recess and a data storage device positioned in the recess. Marsh, in contrast, is not at all related to these unique cytology problems and associated configurations. In contrast, Marsh addresses a very different problem of providing a high density electrical connector between a lap top computer and a desk top computer. Marsh (col. 1, lines 9-11; 31-42). Consequently, Marsh is not analogous art for purposes of the rejection under §103(a).

Applicant notes that the Office Action has not addressed this issue, which was also addressed in Applicant's prior response. Moreover, given the very different devices and applications described in McDevitt and Marsh, a person of ordinary skill in the art would not combine these references.

Accordingly, Applicant respectfully requests that the rejection of claims 8-10 and 25-28 under 35 U.S.C. §103(a) be withdrawn.

VII. Claims 13 and 32 Are Patentable Over McDevitt and Giordano

Dependent claims 13 and 22 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt in view of U.S. Patent No. 5,935,426 to Giordano ("Giordano"). These dependent claims incorporate the elements and limitations of respective independent claims 1 and 18 and, therefore, are also believed allowable. MPEP §2143.03. Giordano is cited for the limited purpose of allegedly disclosing filter expiration data, but does not cure the deficiencies of McDevitt. Accordingly, the cited references, individually and even if somehow properly combined, cannot support the rejection.

It is generally alleged that it would be obvious to add the expiration date of a filter to a data storage means of McDevitt. Final Office Action (p. 6). Giordano, however, is not analogous art. A meter system for a water treatment device is not in the field of Applicant's endeavor of preparing biological specimens. Accordingly, Giordano must be reasonably pertinent to the particular problem with which the inventor is concerned, which it is not. As discussed in the "Description of Related Art," Applicant describes, e.g., improving systems that utilize cytological filters by verifying filter expiration, compatibility with specimens and availability of processing information and operating parameters. Giordano, in contrast, is not at all related to these unique cytology problems. In contrast, Giordano addresses very different problems related to a water treatment device that is attached to a faucet. Giordano (col. 1, lines 45-55). Consequently, Giordano is not reasonably pertinent to the particular cytological problems addressed by embodiments and, therefore is not analogous art for purposes of the rejection under §103(a).

Applicant again notes that the Office Action has not addressed this issue, which was also addressed in Applicant's prior response. Moreover, given the very different devices and applications described in McDevitt (related to a filter for a faucet) and Giordano (related to a laptop connector), a person of ordinary skill in the art would not combine these unrelated references.

Accordingly, Applicant respectfully requests that the rejection of claims 13 and 32 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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